

### **REMARKS**

This is in response to the Official Action dated October 3, 2007, which issued in connection with the above-referenced patent application. Claims 1-14 are pending in this application, claims 15-23 are withdrawn. Claims 1-14 are rejected.

#### **Elections/Restrictions**

Applicant hereby affirms the election of group I, claims 1-14 for prosecution, without traverse, per the telephone conversation between the Examiner and Mr. Skula. Claims 15-23, drawn to a method for the preparation of mineralized collagen particles, are withdrawn from further prosecution in this application. (Office action, p. 3, para. 4).

#### **Objections**

The Examiner objected to claim 4, stating that in line 3, a comma is necessary after the word “mediators”. (Office action, p. 4, para. 5). Applicant has revised claim 4 to include said comma, and the Examiner is respectfully requested to withdraw the objection.

The Examiner objected to claim 8 stating that it depends from itself. The claim has been amended so that it properly depends from claim 3, and the Examiner is respectfully requested to withdraw the objection.

#### **Claim Rejections Under U.S.C. § 112**

The Examiner has rejected claim 1, and also dependent claims 2-14, stating that the phrase “substantially uniformly distributed” is indefinite because it is not certain what is the level of uniformly distributed collagen in a graft. (Office action, p. 5, para. 1). The Examiner also states that no definition or indication of the level of uniformly distributed collagen in a graft is provided in the specification, and that dependent claims 2-14 do not cure this deficiency. (Office action, p. 5, para. 2).

Applicants wish to direct the Examiner's attention to Constantz et al, U.S. Patent 5,231,169 (Constantz '169), which is incorporated by reference in the instant application (page 2 para. 0016), and which discloses a "substantially uniform distribution". For example, Constantz '169 discloses "[t]he product has a substantially uniform distribution of calcium phosphate crystals distributed throughout the collagen fibrils." (Col. 2, lines 15-17), and also "The resulting product after thorough washing in distilled water has calcium phosphate stably distributed with the fibrils to form a substantially uniform composition of calcium phosphate and collagen." (Col. 2, lines 25-28), and also "During the course of the reaction, mild agitation is maintained, so as to ensure substantially uniform mixing of the collagen fibrils and the calcium phosphate mineral." (Col. 3, lines 35-38), and also "[w]ith the calcium distributed uniformly throughout the sample." (Col. 4, lines 64-65). Constantz '169 further discloses that a method of evaluating a "substantially uniform distribution" is to show that it maintains phase separation after four hours in solution (see Col. 4 line 65 through Col. 5, line 3). Thus, the prior art teachings adequately define the terms, and further definition is not required in the instant application. The Examiner is respectfully requested to withdraw the rejection of claims 1-14 under U.S.C. § 112.

The Examiner has rejected claim 4 under U.S.C. § 112, stating that the phrase "thrombin derived peptides" is indefinite since there is no definition in the specification that would define or explain such terms. Applicants wish to direct the Examiner's attention to US Patents 5,355,664 and 5,500,412 by Carney et al., titled "Thrombin derived polypeptides; compositions and methods for use", filed Oct. 31, 1986 and Jan. 21, 1993, respectively. Carney et al. describe the terms "thrombin derived (poly)peptides", and Applicants argue that the terms are understood to have their common meaning as described by Carney et al. The Examiner is respectfully requested to withdraw the rejection of claim 4 under U.S.C. § 112.

#### **Claim Rejections Under U.S.C. § 102**

The Examiner has rejected claims 1-6, 8, 9, 11, 12, and 14 under 35 U.S.C. § 102(b) as being anticipated by Yamamoto et al. U.S. 2002/0183855. Applicant's claim(s) are directed to a flowable composition having "a fluid biocompatible carrier" (claim 1). Yamamoto does not disclose or describe such a carrier. Yamamoto discloses "The mineralized collagen matrix

according to the invention can be easily hydrated by placing the matrix in fluid. The matrix maintains its integrity and shape after hydration. The hydrated matrix can be compressed and manually inserted through a narrow opening but returns to its original size and shape on rehydration.” (see Yamamoto page 5, paragraph 0056). The device disclosed by Yamamoto is directed to a three-dimensionally fixed matrix, and is not a flowable composition (see Yamamoto, claims 1-15, also page 1, paragraph 0014). Applicant argues that the disclosure by Yamamoto et al. U.S. Patent Publication 2002/0183855 does not anticipate applicant’s invention, and the Examiner is respectfully requested to withdraw the rejection under U.S.C. § 102(b).

### **Claim Rejections Under U.S.C. § 103**

The Examiner has rejected claims 1, 6, 7, 10, and 13 under 35 U.S.C. § 103(a) as being unpatentable over Yamamoto et al. U.S. 2002/0183855 in view of Silver et al. U.S. 5,532,217. The Examiner states that the teachings of Silver et al. teach a bone replacement structure that has demineralized matrix and where the collagen fibers can have a diameter of less than a micron and up to several millimeters. (Office action page 6, para. 6). Applicant asserts that Silver does not remedy the deficiencies of Yamamoto because Applicant’s claim(s) are directed at a flowable composition having “a fluid biocompatible carrier” (claim 1), and neither Yamamoto nor Silver disclose a flowable composition having “a fluid biocompatible carrier”. The Examiner is respectfully requested to withdraw the rejection under U.S.C. § 103(a).

Based on the foregoing, applicant believes the application is now in condition for allowance. Favorable reconsideration and notice of allowance are solicited. If any questions arise which can be disposed through interview, the Examiner is encouraged to contact applicants’ attorney at the telephone number listed below.

Please charge any fees, which may be required for this submission to Johnson & Johnson  
Deposit Account No. 10-0750/DEP5286USNP/SBA.

Respectfully submitted,

/Stacey B. Antar/

Stacey B. Antar  
Reg. No. 39,595  
Attorney for Applicant

Johnson & Johnson  
One Johnson & Johnson Plaza  
New Brunswick, NJ 08933  
(732) 524-2824